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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,298	06/12/2006	Gordon N. Gill	00015-041US1/2003-061-1M1	6198
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Joseph R. Baker, APC Gavrilovich, Dodd & Lindsey LLP 4660 La Jolla Village Drive, Suite 750 San Diego, CA 92122			EXAMINER SWOPE, SHERIDAN	
			ART UNIT	PAPER NUMBER
			1652	
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			04/21/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/552,298

**Applicant(s)**

GILL ET AL.

**Examiner**

SHERIDAN SWOPE

**Art Unit**

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 March 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 11-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SG/US)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Applicants' filing of March 24, 2009, in response to the Action of November 24, 2008, is acknowledged. It is acknowledged that Claims 1 and 2 have been amended. Claims 1-42 are pending. Claims 11-42 were previously withdrawn from further consideration as being drawn to nonelected inventions. Claims 1-10 are hereby examined.

#### ***Priority***

The priority date granted for the instant invention is April 1, 2004, the filing date of PCT/US04/10218, which disclosed the elected invention. It was previously noted that provisional application US 60/459,786 fails to disclose SEQ ID NO: 1 or 2. In response, applicants argue that the specification at pages, 8, 13, and 34-35 as well as Figure 1 disclose SCP1. It is acknowledged that pages 8 and 13 given some physical properties of the encoded protein, that pages 34-35 given a genomic sequence, and Figure 1 provides alignment of protein fragments. However, said evidence fails to provide the complete sequence for SEQ ID NO: 1 or 2. Therefore, the priority date granted for the instant invention is April 1, 2004.

#### ***Specification-Objections***

Objection to the specification for disclosing sequences that are not identified by a sequence identifier number (SEQ ID NO: ), is maintained. It is acknowledged that Applicants have filed an amendment. However, said amendment has typographical errors which make the sequence indefinite. See, for example, page 3, pargs 2-3.

#### ***Claims-Objections***

Objection to Claims 5-10, for reciting non-elected sequences, is maintained.

***Claim Rejections - 35 USC § 112-Second Paragraph***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Rejection of Claims 1 and 5-10 under 35 U.S.C. 112, second paragraph, because the phrase “conservative substitutions” renders the claims indefinite, is maintained. Applicants argue that the skill in the art is high and the specification set forth exemplary conservative amino acid substitution. This is not found to be persuasive. Although very common in the art, the term “conservative substitution” is vague and indefinite for the reasons explained in the prior actions. The exemplary disclosure does not teach the metes and bounds of a recited invention.

Rejection of Claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for reciting a series of nucleic acid molecules by GenBank Accession numbers is maintained. Applicants did not comment on this rejection.

***Claim Rejections - 35 USC § 112-First Paragraph***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Enablement**

Rejection of Claims 1 and 7-10 under 35 U.S.C. 112, first paragraph/enablement, for reasons explained in the prior action, is maintained. In support of their request that this rejection be withdrawn, Applicants provide the following arguments.

The Examiner takes the position that Applicants are not enabled but then goes on to indicate that Cocks et al. in view of Meinnel et al. would be enabled to (i) select one of numerous

(almost infinite) polypeptides sequences from Cocks et al., (ii) identify one sequence that would have a stop codon from an almost infinite number of sequences in the correct reading frame and then (iii) insert upstream at one of almost an infinite number of points a starting methionine. The Examiner appears to indicate that Applicants are not entitled to adding or substituting amino acids having a defined structure and function using routine skill in the art, but Cocks et al. in view of Meinnel et al. are entitled to random selection of an infinite number of polypeptides to arrive at Applicants' claimed invention having structure but which is not functionally defined to be a kinase.

These arguments are not found to be persuasive for the following reasons. (i) As explained in the Action of April 21, 2008, Cocks teaches a specific cDNA comprising SEQ ID NO: 1, except for a codon encoding the N-terminal methionine residue. The polynucleotide of Cocks has a stop codon at the end. The fact that Cocks teaches other sequences is irrelevant. (ii) The examiner is unclear as to what is meant here. The polynucleotide of Cocks has a stop codon at the end. (iii) As explained in the Action of April 21, 2008, Meinnel et al teaches what is well-known in the art; that essentially all protein translation begins with an N-terminal methionine.

The teachings of Cocks and Meinnel render obvious adding three specific nucleotides to the 5'-end of the cDNA of Cocks, which would add one specific methionine residue to the N-terminal end of the encoded protein. Said modification is limited; it does not encompass, for example, making and testing any polypeptide having at least 80% identity with the polypeptide encoded by Cock's cDNA.

For these reasons and those explained in the prior action, rejection of Claims 1 and 7-10 under 35 U.S.C. 112, first paragraph/enablement, is maintained.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Rejection of Claims 1 and 5-10 under 35 U.S.C. 102(b), as being anticipated by Venter et al, 2002 for the reasons explained in the prior action, is maintained. In support of their request that this rejection be withdrawn, Applicants provide the following arguments. Venter et al does not teach or suggest that their polynucleotide encodes a protein having a recited activity. This is the same argument Applicants provided in their prior response. See the Action of November 24, 2008 as to why this argument is not persuasive.

Since it is unclear what specific sequences are recited in Claim 2, analysis under 35 U.S.C. 102(b) and 103(a) is not possible at this time. Upon clarification as to what specific sequences are recited in Claim 2, any subsequent rejection under 35 U.S.C. 102(b) or 103(a) will not be considered a new grounds for rejection.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Rejection of Claims 1, 3, 4, and 5-10 under 35 U.S.C. 103(a) as being unpatentable over Cocks et al, 2003 in view of Meinnel et al, 1993, for the reasons explained in the prior action, is

maintained. In support of their request that this rejection be withdrawn, Applicants provide the following arguments.

(A) The Cocks et al. patent is a listing of putative sequences that may or may not have activity, that may or may not have start codons and may or may not have stop codons. SEQ ID NO:843, which is relied upon for the present rejection is a sequence of nearly 2000 basepairs of which only half appear to align. Applicants submit that there is no teaching or suggestion in Cocks et al. that identify a sequence set forth by Applicants having the biological activity as set forth in the claims.

(B) In order to overcome the deficiencies of Cocks et al., the Office Action combines Meinnel et al. for the teaching that nearly all proteins begin with an N- terminal Methionine. Furthermore, Meinnel et al. indicates that "most" have such a methionine, clearly some do not.

(C) As stated above, the Cocks et al. disclosure is a non-enabling disclosure for at least two reasons. First, a sequence lacking a functional utility lacks enablement (see, e.g., *In re Fisher* (Fed. Cir. 2005)). Second, the Examiner attributes enablement only to the extent that a proper start codon is inserted in any number of infinitely possible positions upstream of the sequence identified in Cocks et al. For Cocks et al. and Meinnel et al. to be enabling would require modification of their defective sequence to arrive at Applicants' invention.

(A) Reply: This argument is essentially the same as the argument Applicants provided in their prior response. See the Action of November 24, 2008 as to why this argument is not persuasive.

(B) Reply: The skilled artisan would believe that, more likely than not, the polypeptide encoded by the polynucleotide of Cocks begins with a methionine residue.

(C) Reply: This is a rejection under 35 USC 103(a), not 35 USC 112/enablement. As explained in the prior action, it is not necessary for Cocks et al to teach the activity of the polypeptide encoded by their sequence. The polynucleotide rendered obvious by Cocks et al and Meinnel et al comprises SEQ ID NO: 1 and, thus, inherently has the recited activity. Cocks teaches that their polynucleotide begins with 5'-GGA and ends with TAG-3', indicating that, within the 2302 base pair sequence, the specific 5'-GGA.... TAG-3' sequence represents a protein-encoding cDNA.

For these reasons and those explained in the prior action, rejection of Claims 1, 3, and 5-10 under 35 U.S.C. 103(a) as being unpatentable over Cocks et al, 2003 in view of Meinnel et al, 1993, is maintained.

***Allowable Subject Matter***

No claims are allowable.

Applicant's amendment necessitated any new grounds of rejection presented in this Office action. Any new references were cited solely to support rejection(s) based on amendment or rebut Applicants' arguments. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37



CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Regarding filing an Appeal, Applicants are referred to the Official Gazette Notice published July 12, 2005 describing the Pre-Appeal Brief Review Program.

### **Final Comments**

To insure that each document is properly filed in the electronic file wrapper, it is requested that each of amendments to the specification, amendments to the claims, Applicants' remarks, requests for extension of time, and any other distinct papers be submitted on separate pages.

It is also requested that Applicants identify support, within the original application, for any amendments to the claims and specification.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan L. Swope whose telephone number is 571-272-0943. The examiner can normally be reached on M-F; 9:30-7 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashed can be reached on 571-272-0934. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published application may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

Art Unit: 1652

system, see <http://pair-direct.uspto.gov>. Should you have questions on the access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/SHERIDAN SWOPE/  
Primary Examiner, Art Unit 1652